

SEP 27 2004

(Modified)

Application No.: 10/700,909

Filing Date: 11/04/2003

Applicant: John R. Erbey II, et al.

Title: Methods and Therapeutic Combinations for the Treatment of Autoimmune Disorders

Certificate of Mailing under 37 CFR 1.8

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Commissioner for Patents
P.O. Box 1450
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Date



Signature

Ann Marie Cannoni, Reg. No. 35,972

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Documents enclosed:

Certificate of Mailing PTO/SB/92 -1 Page

Information Disclosure Statement - 3 Pages

Form PTO 1449 - 16 Pages

390 References (for a total of 6 Boxes)

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JFW

PATENT CASE CV06093US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

John R. Erbey II, et al.

: Examiner: To Be Assigned

For:

Methods and Therapeutic Combinations

: Group Art Unit: 1614

for the Treatment of Autoimmune Disorders

: Date: September 24, 2004

Serial No.: 10/700,909

Filed: 11/04/2003
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request that the following be considered and made record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

Pursuant to Rule 56, it is requested that the documents listed on the accompanying PTO-1449 Form be considered and made of record in the above-identified patent

application. Copy(ies) of these references ☒ are attached ☐ were filed in related application U.S. Serial No(s) _____ filed _____, respectively.

(b) No fee is believed due because:

- ☐ This Information Disclosure Statement is being filed within three (3) months of the filing date of the application.
- ☐ This Information Disclosure Statement is being concurrently filed with the above-identified application.
- ☐ This Information Disclosure Statement is being concurrently filed with a Request for Continued Examination (RCE).
- ☒ This Information Disclosure Statement is being filed prior to the mailing of a first Office Action on the merits.

(c) ☐ This Information Disclosure Statement is being filed before the mailing date of any final action, notice of allowance or an action that otherwise closes prosecution; and

☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

(d) ☐ This Information Disclosure Statement is being filed on or before the payment of the issue fee; and

☐ Each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

☐ The Commissioner is hereby authorized to charge the requisite fee listed on the attached Fee Transmittal Sheet.

Serial No. 10/700,909

September 24, 2004


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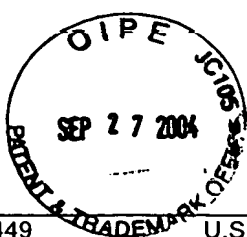
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 19-0395, Patent Case No. CV06093US01.

Respectfully submitted,
SCHERING-PLOUGH CORPORATION

Dated: **September 24, 2004**
SCHERING-PLOUGH CORPORATION
Patent Department, K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530
Facsimile No.: (908) 298-5388

By:


Name: **Ann M. Cannoni**
Reg. No.: **35,972**
Attorney of Record
Telephone No.: (908) 298-5024



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:
CV6093US01

APPLICATION NO.:
10/700, 909
**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

APPLICANT:
John R. Erbey II, et al.

FILING DATE:
11/04/2003

GROUP:
1614
(Use several sheets if necessary)
FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATIO N	
							YES	N O
	AA	BE 884722 A	12/01/80	BELGIUM	C07D	AG1K	X(abs.)	
	AB	CA 2253769	11/29/99	CANADA	A61K	31/22		
	AC	DE 2046823 A	03/30/72	GERMANY	C07C		X(abs.)	
	AD	DE 2521113 A	03/18/76	GERMANY	C07C	87/34	X(abs.)	
	AE	EP 0002151 A1,B1	05/30/79	EUROPE	C07C	69/67		
	AF	EP 0010299 B1	02/15/84	EUROPE	A61K	45/06		
	AG	EP 0179559 A2	04/30/86	EUROPE	C07D	405/06		
	AH	EP 0199630 A1	10/29/86	EUROPE	C07D	205/08		
	AI	EP 0199630 B1	09/19/90	EUROPE	C07D	205/08		
	AJ	EP 0264231 A1	04/20/88	EUROPE	C07D	205/08		
	AK	EP 0266896 B1	05/11/88	EUROPE	C07D	471/04		
	AL	EP 0274873 B1	07/20/88	EUROPE	C07K	11/00		
	AM	EP 0288973 B1	11/02/88	EUROPE	C07D	417/06		
	AN	EP 0311366 B1	04/12/89	EUROPE	C07D	471/04		
	AO	EP 0333268 A1	09/20/89	EUROPE	C07F	7/18		
	AP	EP 0337549 A1	10/18/89	EUROPE	C07D	205/08		
	AQ	EP 0337549 B1	10/04/95	EUROPE	C07D	205/08		
	AR	EP 0365364 A2	04/25/90	EUROPE	C07D	205/08		
	AS	EP 0369686 A1	05/23/90	EUROPE	C07D	463/00		
	AT	EP 0375527 A1	06/27/90	EUROPE	C07D	205/08	X(abs.)	
	AU	EP 0401705 A3	12/12/90	EUROPE	A61K	31/66		
	AV	EP 0415487 A2	03/06/91	EUROPE	C07D	205/08		
	AW	EP 0455042 A1	11/06/91	EUROPE	A61K	31/19		
	AX	EP 0457514 A1	11/21/91	EUROPE	A61K	45/06		
	AY	EP 0457514 B1	08/21/96	EUROPE	A61K	45/06		
	AZ	EP 0461548 A3	12/18/91	EUROPE	A61K	31/365		
	BA	EP 0462667 A2	12/27/91	EUROPE	C07D	205/08		
	BB	EP 0475148 A1	03/18/92	EUROPE	A61K	31/215		
	BC	EP 0475755 B1	03/18/92	EUROPE	C07D	403/06		
	BD	EP 0481671 A1	04/22/92	EUROPE	C07D	205/08		
	BE	EP 0482498 A3	04/29/92	EUROPE	A61K	31/66		
	BF	EP 0524595 A1	01/27/93	EUROPE	C07D	205/08		
	BG	EP 0720599 B1	07/10/96	EUROPE	C07D	205/08		
	BH	EP 0793958 A2	09/10/97	EUROPE	A61K	9/16	X(abs)	
	BI	EP 0814080 A1	12/29/97	EUROPE	C07D	267/14		
	BJ	EP 0904781 A2	03/31/99	EUROPE	A61K	31/215		
	BK	EP 1048295 A2	11/02/00	EUROPE	A61K	31/216		
	BL	FR 1103113	10/31/55	FRANCE				X
	BM	FR 2779347	12/10/97	FRANCE	A61	31/215	X(abs.)	
	BN	GB 861367	02/22/61	GB	A61K			
	BO	GB 902658	08/09/62	GB	C07D			
	BP	GB 1415295	11/26/75	GB	C07C	59/26		



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:

CV06093US01

APPLICATION NO.:

10/700,909

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT:

John R. Erbey II, et al.

FILING DATE:

11/04/2003

GROUP:

1614

FOREIGN PATENT DOCUMENTS

BQ	GB 2329334 A	03/24/99	GB	A61K	45/00		
BR	JP 028057	10/01/81	JAPAN			X(abs.)	
BS	JP 121479	12/10/86	JAPAN			X(abs.)	
BT	JP 136485	05/26/81	JAPAN			X(abs.)	
BU	JP 180212	03/24/86	JAPAN			X(abs.)	
BV	JP 219681	04/14/87	JAPAN			X(abs.)	
BW	JP 5194209 A	08/03/93	JAPAN	A61K	031/22	X(abs.)	
BX	JP 5239020 A	1993	JAPAN	C07D	205/08	X(abs.)	
BY	JP 4054182 A	1992	JAPAN	C12P	017/16	X(abs.)	
BZ	JP 63017859 A	1988	JAPAN	C07D	205/08	X(abs.)	
CA	JP 4266869 A	1992	JAPAN	C07D	205/08	X(abs.)	
CB	JP 4356195 A	1993	JAPAN			X(abs.)	
CC	JP 4356495	12/10/92	JAPAN			X(abs.)	
CD	JP 5058993 A	1993	JAPAN			X(abs.)	
CE	JP 61280295 A	1987	JAPAN			X(abs.)	
CF	JP 95051558 B2	06/05/95	JAPAN	C07D	205/08	X(abs.)	
CG	JP 91068020	10/25/91	JAPAN	C07D	205/08	X(abs.)	
CH	JP 94047573	06/22/94	JAPAN	C07D	205/08	X(abs.)	
CI	WO 82/01649	05/27/82	PCT	A61K	9/52	X(abs.)	
CJ	WO 87/04429	07/30/87	PCT	C07D	205/08		
CK	WO 88/04656	06/30/88	PCT	C07D	405/04		
CL	WO 88/05296	07/28/88	PCT	A61K	31/365		
CM	WO 91/03249	03/21/91	PCT	A61K	31/785	X(abs.)	
CN	WO 92/13837	08/20/92	PCT	C07D	205/08		
CO	WO 93/02048	02/04/93	PCT	C07D	205/08		
CP	WO 93/07167	04/15/93	PCT	C07J	71/00		
CQ	WO 93/11150	06/10/93	PCT	C07J	71/00		
CR	WO 94/00480	01/06/94	PCT	C07J	71/00		
CS	WO 94/14433	07/07/94	PCT	A61K	31/395		
CT	WO 94/17038	08/04/94	PCT	C07D	205/12		
CU	WO 94/20535	09/15/94	PCT	C07K	13/00		
CV	WO 95/04533	02/16/95	PCT	A61K	31/445		
CW	WO 95/06470	03/09/95	PCT	A61K	31/435		
CX	WO 95/08532	03/30/95	PCT	C07D	205/08		
CY	WO 95/18143	07/6/95	PCT	C07J	71/00		
CZ	WO 95/26334	10/05/95	PCT	C07D	205/08		
DA	WO 95/28919	11/02/95	PCT	A61K	31/19	X(abs.)	
DB	WO 95/35277	12/28/95	PCT	C07D	205/08		
DC	WO 96/00288	01/04/96	PCT	C12N	15/12		
DD	WO 96/09827	04/04/96	PCT	A61K	31/58		
DE	WO 96/16037	05/30/96	PCT	C07D	205/08		

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01		APPLICATION NO.: 10/700,909	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>				APPLICANT: John R. Erbey II, et al.			
				FILING DATE: 11/04/2003		GROUP: 1614	
FOREIGN PATENT DOCUMENTS							
	DF	WO96/19450	06/27/96	PCT	C07D	205/08	
	DG	WO 96/19987	07/04/96	PCT	A61K	31/35	
	DH	WO 96/40255	12/19/96	PCT	A61K	45/06	
	DI	WO 97/16455	05/09/97	PCT	C07H	3/04	
	DJ	WO 97/18304	05/22/97	PCT	C12N	15/00	
	DK	WO 97/25042	07/17/97	PCT	A61K	31/42	
	DL	WO 97/28149	08/07/97	PCT	C07D	307/79	
	DM	WO 97/31907	09/04/97	PCT	C07D	263/56	
	DN	WO 97/35576	10/02/97	PCT	A61K	31/44	
	DO	WO 97/46238	12/11/97	PCT	A61K	31/245	
	DP	WO 98/01100	01/15/98	PCT	A61K		
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	EC	WO 99/08501	2/25/99	PCT			
	ED	WO 99/09967	03/04/99	PCT	A61K	31/00	
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	EG	WO 99/15159	04/01/99	PCT	A61K	31/00	
	EH	WO 99/15520	04/01/99	PCT	C07D	319/20	X(abs.)
	EI	WO 99/18072	04/15/99	PCT	C07D	205/08	
	EJ	WO 99/20275	04/29/99	PCT	A61K	31/47	
	EK	WO 99/20614	04/29/99	PCT	C07D	265/36	
	EL	WO 99/29300	06/17/99	PCT	A61K	9/107	
	EM	WO 99/38498	08/05/99	PCT	A61K	31/00	
	EN	WO 99/38845	08/05/99	PCT	C07D	213/65	
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	EP	WO 99/46232	09/16/99	PCT	C07C	62/34	X(abs.)
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	ER	WO 99/48488	09/30/99	PCT	A61K	31/00	
	ES	WO 99/66929	12/29/99	PCT	A61K	31/405	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i>				ATTY. DOCKET NO.: CV06093US01		APPLICATION NO.: 10/700,909	
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				FILING DATE: 11/04/2003		GROUP: 1614	
FOREIGN PATENT DOCUMENTS							
	ET	WO 99/66930	12/29/99	PCT	A61K	31/405	
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	EV	WO 00/07617	02/17/00	PCT	A61K	38/26	
	EW	WO 00/16749	03/30/00	PCT	A61K	9/16	X(abs.)
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	EZ	WO 00/18395	04/06/00	PCT	A61K	31/215	
	FA	WO 00/20623	04/13/00	PCT	C12P	41/00	
	FB	WO 00/23415	04/27/00	PCT	C07C	69/734	
	FC	WO 00/23416	04/27/00	PCT	C07C	69/734	
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	FG	WO 00/28981	05/25/00	PCT	A61K	31/00	
	FH	WO 00/31548	06/02/00	PCT	G01N	33/68	
	FI	WO 00/32189	06/08/00	PCT	A61K	31/415	
	FJ	WO 00/34240	06/15/00	PCT	C07D	205/08	
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	FL	WO 00/37078	06/29/00	PCT	A61K	31/44	X(abs.)
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	FU	WO 00/38729	07/06/00	PCT	A61K	45/06	
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	GC	WO 00/57859	10/05/00	PCT	A61K	9/48	
	GD	WO 00/57918	10/05/00	PCT	A61K	47/44	
	GE	WO 00/60107	10/12/00	PCT	C12P	17/10	
	GF	WO 00/63153	10/26/00	PCT	C07C	69/734	
	GG	WO 00/63161	10/26/00	PCT	C07C	237/30	

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01		APPLICATION NO.: 10/700,909	
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				FILING DATE: 11/04/2003		GROUP: 1614	
FOREIGN PATENT DOCUMENTS							
	GH	WO 00/63190	10/26/00	PCT	C07D	265/38	
	GI	WO 00/63196	10/26/00	PCT	C07D	277/04	
	GJ	WO 00/63209	10/26/00	PCT	C07D	471/04	
	GK	WO 00/63703	10/26/00	PCT	G01N	33/92	
	GL	WO 00/69412	11/23/00	PCT	A61K	9/127	
	GM	WO 00/69445	11/23/00	PCT	A61K	31/785	
	GN	WO 00/72825	12/7/00	PCT	A61K	9/14	
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	GT	WO 00/78313	12/28/00	PCT	A61K	31/422	
	GU	WO 01/00579	01/04/01	PCT	C07D	213/65	
	GV	WO 01/00603	01/04/01	PCT	C07D	277/24	
	G W	WO 01/08686	02/08/01	PCT	A61K	31/495	
	GX	WO 01/12176	02/22/01	PCT	A61K	31/16	
	GY	WO 01/12187	02/22/01	PCT	A61K	31/404	
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	HA	WO 01/14349	03/01/01	PCT	C07D	277/34	X(abs.)
	HB	WO 01/14350	03/01/01	PCT	C07D	277/34	X(abs.)
	HC	WO 01/14351	03/01/01	PCT	C07D	277/34	X(abs.)
	HD	WO 01/15744	03/08/01	PCT	A61K	49/00	
	HE	WO 01/16120	03/08/01	PCT	C07D	263/32	
	HF	WO 01/17994	03/15/01	PCT	C07D	413/12	
	HG	WO 01/18210	03/15/01	PCT	C12N	15/12	
	HH	WO 01/21181	03/29/01	PCT	A61K	31/675	X(abs.)
	HI	WO 01/21259	03/29/01	PCT	A61P		
	HJ	WO 01/21578	03/29/01	PCT	C07C	235/60	X(abs.)
	HK	WO 01/21647	03/29/01	PCT	C07K	14/00	
	HL	WO 01/22962	04/05/01	PCT	A61K	31/435	
	HM	WO 01/25225	04/12/01	PCT	C07D	317/18	
	HN	WO 01/25226	04/12/01	PCT	C07D	327/04	
	HO	WO 01/30343	05/03/01	PCT	A61K	31/40	
	HP	WO 01/32161	05/10/01	PCT	A61K	31/00	
	HQ	WO 01/35970	05/25/01	PCT	A61K	35/76	
	HR	WO 01/40192	06/07/01	PCT	C07D	217/26	X(abs.)

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FOREIGN PATENT DOCUMENTS							
	HS	WO 01/45676	06/28/01	PCT	A61K	9/24	
	HT	WO 01/49267	07/12/01	PCT	A61K	9/14	
	HU	WO 01/64221	09/07/01	PCT	A61K	31/52	
	HV	WO 01/76632	10/18/01	PCT	A61K	45/06	
	HW	WO 02/50090	06/27/02	PCT	C07H	15/26	
	HX	WO 02/058696	08/01/02	PCT	A61K	31/397	
	HY	WO 02/058731	08/01/02	PCT	A61K	45/06	
	HZ	WO 02/058732	08/01/02	PCT	A61K	45/06	
	IA	WO 02/058733	08/01/02	PCT	A61K	45/06	
	IB	WO 02/058734	08/01/02	PCT	A61K	45/06	
	IC	WO 02/058685	08/01/02	PCT	A61K	31/00	
	ID	WO 02/064130	08/22/02	PCT	A61K	31/195	
	IE	WO 02/064549	08/22/02	PCT	C07C	275/34	
	IF	WO 02/064664	08/22/02	PCT	C08G	77/02	
	IG	WO 02/072104	09/19/02	PCT	A61K	31/54	
	IH	WO 02/081454	10/17/02	PCT	C07D	239/36	
	II	WO 02/26729	04/04/02	PCT	C07D	311/66	
	IJ	WO 02/064094	08/22/02	PCT	A61K		
	IK	WO 02/50027	06/27/02	PCT			
	IL	WO 02/50060	06/27/02	PCT			
	IM	WO 02/50068	06/27/02	PCT			
	IN	WO 94/26738	11/24/94	PCT			
	IO	EP 1 036 563 A1	09/20/00	EPO			
	IP	EP 0 753 298 A1	01/15/97	EPO			
	IQ	WO 01/34148	05/17/01	PCT			
	IR	WO 01/60807	08/23/01	PCT			
	IS	WO 02/08188	01/31/02	PCT			
	IT	WO 03/039542	05/15/03	PCT			
	IU	WO 03/074101	09/12/03	PCT			
	IV	WO 03/088962	10/30/03	PCT			
	IW	WO 03/018024	03/06/03	PCT	A61K	31/55	
	IX	WO 03/018059	03/06/03	PCT	A61K	45/06	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	IY	Exhibit A: SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary		
	IZ	Exhibit B: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JA	Exhibit C: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JB	Exhibit D: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JC	Exhibit E: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JD	Exhibit F: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JE	Exhibit G: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JF	Exhibit H: SCH 58235 (ezetimibe), Drug Formulation Development Summary		
	JG	Exhibit 1: Master Sheet for the SCH 58235 and Lovastatin Research Study, <i>Schering-Plough Research Institute</i> (Protocol No. C906-411), page 1576-1585		
	JH	Exhibit 2: Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, <i>Peninsular Testing Corporation</i> , page 106-112		
	JI	Exhibit 3: Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," <i>Schering-Plough Research Institute</i> (Protocol No. C98-010), page 1558-1566		
	JJ	Exhibit 4: Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, <i>Peninsular Testing Corporation</i> , page 124-130		
	JK	Exhibit 5: Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," <i>Schering-Plough Research Institute</i> , page 1-8		
	JL	Vaccaro, W.D. <i>et al.</i> , "Sugar-substituted 2-azetidinone cholesterol absorption inhibitors: enhanced potency by modification of the sugar" <i>Bioorganic & Medicinal Chemistry Ltrs., Oxford, G.B.</i> , 8:313-318 (1998)		
	JM	Vaccaro, W.D. <i>et al.</i> , "Carboxy-substituted 2-azetidinones as cholesterol absorption inhibitors", <i>Bioganic & Medicinal Chem. Ltrs. Oxford, G.B.</i> 8:319-322 (1998)		
	JN	H. Davis <i>et al.</i> , "Ezetimibe, a Potent Cholesterol Absorption Inhibitor, Inhibits the Development of Atherosclerosis in Apo E Knockout Mice", <i>Arterioscler, Thromb. Vasc. Biol</i> 21:2032-2038, (Dec. 2001)		
	JO	Simova, E., "Aldol-type addition of hydrocinnamic acid esters to benzylideneaniline", <i>Chemical Abstracts No. 15</i> , 86 (April 11, 1997)		
	JP	Otto <i>et al.</i> , "Stereochemistry of dehydration and halogenation of αR^* and αS^* isomeric 3-(α -hydroxybenzyl)-1,4 diphenyl-2 azetidinones, <i>Chemical Abstracts No. 19</i> , 99 (Nov. 7, 1983)		
	JQ	T. Durst <i>et al.</i> , "Metallation of N-Substituted β -Lactams. A Method of the Introduction of 3-substituents into β -Lactams" <i>Canadian Journal of Chemistry</i> , 50:3196-3201 (1971)		
	JR	Nobuki, O. <i>et al.</i> , "Stereoselective syntheses of β -lactam derivatives by ultrasound promoted Reformatskii reaction" <i>Chemical Abstracts No. 106</i> , 17 (April 27, 1987)		
	JS	M. Hoekman, <i>et al.</i> , "Synthesis of Homologues of 4,5-Dihydroxy-and 4-Hydroxy-5-oxohexanoic Acid γ -Lactones", <i>J. Agric. Food Chem.</i> , 30:920-024 (1982)		

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: CV06093US01	APPLICATION NO.: 10/700,909
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	JT	H. Otto <i>et al.</i> "Darstellung and Stereochemie von 3-(α -Hydroxybenzyl)-1,4-diphenyl-2-azetidononen", <i>Liebigs Ann. Chem.</i> 1152-1161 (1983)		
	JU	G. George <i>et al.</i> "3-(1'-Hydroxyethyl)-2-Azetidinones From 3-Hydroxybutyrates and N-Arylaldimines" <i>Tetrahedron Letters</i> , 26 :3903-3906 (1985)		
	JV	Hart <i>et al.</i> "An Enantioselective Approach to Carbapenem Antibodies: Formal Synthesis of (+)-Thienamycin", 26 <i>Tetrahedron Letters</i> , 45 :5493-5496 (1985)		
	JW	Panfil, I. <i>et al.</i> "Synthesis of β -Lactams from α , β -Unsaturated Sugar δ -Lactones" 24 <i>Heterocycles</i> 6 :1609-1617 (1986)		
	JX	D. Roger Illingworth, "An Overview of Lipid-Lower Drugs" <i>Drugs</i> 36 :63:71 (1988)		
	JY	Joseph L. Witztum, M.D., "Current Approaches to Drug Therapy for the Hypercholesterolemic Patient" <i>Circulation</i> 80 :1101-1114 (1989)		
	JZ	B. Ram <i>et al.</i> "Potential Hypolipidemic agents:Part V", 29B Indian J. Chem. 1134-37 (1990)		
	KA	Schnitzer-Polokoff, R. <i>et al.</i> , "Effects of Acyl-CoA: Choleseraol O-Acyltransferase Inhibition on Cholesterol Absorption and Plasma Lipoprotein Composition in Hamsters" <i>Comp. Biochem. Physiol.</i> 99A :665-670 (1991)		
	KB	Horie, M. <i>et al.</i> , "Hypolipidemic effects of NB-598 in dogs" <i>Atherosclerosis</i> 88 :183-192 (1991)		
	KC	Baxter, A., "Squalestatin 1, a Potent Inhibitor of Squalene Synthase, Which Lowers Serum Cholesterol in Vivo", <i>The Journal of Biological Chemistry</i> 267 :11705-11708 (1992)		
	KD	Summary Factfile, "Anti-Antherosclerotic Agents" <i>Current Drugs Ltd.</i> (1992)		
	KE	Harwood H. James, "Pharmacologic consequences of cholesterol absorption inhibition: alteration in cholesterol metabolism and reduction in plasma cholesterol concentration induced by the synthetic saponin β -tigogenin cellobioside (CP-88818; tiqueside) 1" <i>Journal of Lipid Research</i> 34 :377-395 (1993)		
	KF	Salisbury, B. <i>et al.</i> , "Hypocholesterolemic activity of a novel inhibitor of cholesterol absorption, SCH 48461" <i>Atherosclerosis</i> 115 :45-63 (1995)		
	KG	Clader, J. W. <i>et al.</i> , "Substituted (1,2-Diarylethyl)amide Acyl-CoA:Cholesterol Acyltransferase Inhibitors: Effect of Polar Groups in Vitro and in Viro Activity" <i>Journal of Medicinal Chemistry</i> 38 :1600-1607 (1995)		
	KH	Sybertz, E., "Sch 48461, a novel inhibitor of cholesterol absorption" <i>Atherosclerosis</i> pp. 311-315 (1995)		
	KI	Vaccaro, W, <i>et al.</i> , "2-Azetidinone Cholesterol Absorption Inhibitors; Increased Potency by Substitution of the C-4 Phenyl Ring", <i>Bioorg. & Med. Chem.</i> 6 :1429-1437 (1998)		
	KJ	G. Wu <i>et al.</i> , "A Novel One-Step Diastereo-and enantioselective formation of trans-azetidinones and its application to the total synthesis of cholesterol absorption inhibitors A.C.S. (4/21/99).		
	KK	B. Staels, "New Roles for PPARS in Cholesterol Homeostasis", <i>Trends in Pharmacological Sciences</i> , 22 :9 p. 444 (Sept. 2001)		
	KL	Abbott <i>et al.</i> , "Tricor® Capsules, Micronized", <i>Physicians Desk Reference</i> , January 8, 2001.		
	KM	M. Feher <i>et al.</i> , 1991, <i>Lipids and Lipid Disorders</i> , p.1-87 (1991).		

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01	APPLICATION NO.: 10/700,909
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	KN	M. Ricote <i>et al.</i> , "New Roles for PPARs in Cholesterol Homeostasis", <i>Trends in Pharmacological Science</i> , Vol. 22, No. 9 44-443 (2001)			
	KO	C. Dujovne <i>et al.</i> , "Reduction of LDL Cholesterol in Patients with Primary Hypercholesterolemia by SCH 48461: Results of a multicenter Dose-Ranging Study", <i>J. Clin. Pharm.</i> 41:1 70-78 (Jan. 2001)			
	KP	W. Oppolzer <i>et al.</i> , "Asymmetric Diels – Alder Reactions, Facile Preparation and Structure of Sulfonamido – Isobornyl Acrylates", <i>Tetrahedron Letters</i> No. 51, 25:5885-5888 (1984).			
	KQ	M. Davidson <i>et al.</i> , "Colesevelam Hydrochloride: a non-absorbed, polymeric cholesterol lowering agent", <i>Expert Opinion Investigating Drugs</i> , 11:2663-71, (Nov. 2000)			
	KR	M. Davidson <i>et al.</i> , "Colesevelam hydrochloride (cholestagel): a new, potent bile acid sequestrant associated with a low incidence of gastrointestinal effects", 159 <i>Arch. Intern. Med.</i> 16 1893-900 (Sept. 1999)			
	KS	I. Wester, "Cholesterol – Lowering effect of plant sterols", <i>Euro. J. Lipid, Sci. Tech.</i> 37-44 (2000).			
	KT	A. Andersson <i>et al.</i> , "Cholesterol –lowering effects of a stanol ester-containing low fat margarine used in conjunction with a strict lipid-lowering diet", 1 <i>European Heart. J. Supplements</i> S80 - S90 (1999)			
	KU	H. Gylling <i>et al.</i> , "Reduction of Serum Cholesterol in Postmenopausal Women with Previous Myocardial Infarction and Cholesterol Malabsorption induced by Dietary Sitostanol Ester Margarine, 96 <i>Circulation</i> 12 4226-4231 (Dec. 16, 1997)			
	KV	T. Miettinen <i>et al.</i> , "Reduction of Serum Cholesterol with Sitostanol-Ester Margarine in a Mildly Hypercholesterolemic Population", <i>New England Journal of Med.</i> 333 1308-1312 (Nov. 16, 1995)			
	KW	T. Bocan <i>et al.</i> , "The ACAT Inhibitor Avasimibe Reduces Macrophages and Matrix Metalloproteinase Expression in Atherosclerotic Lesions of Hypercholesterolemic Rabbits", <i>Arterioscler Thromb Vasc. Biol.</i> 70-79 (Jan. 2000)			
	KX	M. Van Heek <i>et al.</i> , "In Vivo Metabolism – Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH 58235, in the Rat and Rhesus Monkey through the identification of the active metabolites of SCH48461," 283 <i>J. Pharma and Experimental Therapeutics</i> 1 157-163 (1997)			
	KY	H. Davis <i>et al.</i> , "The Cholesterol Absorption Inhibitor Ezetimibe Inhibits the Development of Atherosclerosis in apo E knockout (-/-) mice fed low fat and western diets," 151 <i>Atherosclerosis</i> 1:133 (July 2000)			
	KZ	L. Nguyen <i>et al.</i> , "Unexpected Failure of Bile Acid Malabsorption to Stimulate Cholesterol Synthesis in Sitosterolemia with Xanthomatosis", 10 <i>Atherosclerosis</i> 2, 289-297 (1990)			
	LA	L. Nguyen <i>et al.</i> , "Regulation of Cholesterol Biosynthesis in Sitosterolemia: effects of lovastatin, Cholestyramine, and dietary sterol restriction," 32 <i>J. Lipid Res.</i> 1941-1948 (1991)			
	LB	M. Cobb <i>et al.</i> , "Sitosterolemia: Opposing Effects of cholestyramine and Lovastatin on Plasma Sterol Levels in a Homozygous Girl and Her Heterozygous Father," 45 <i>Metabolism</i> 6 673-679 (June 1996)			

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OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>				
	LC	M. Huettinger <i>et al.</i> , "Hypolipidemic Activity of HOE-402 is mediated by Stimulation of the LDL Receptor Pathway", <i>13 Arteriosclerosis and Thrombosis</i> 7 1005-1012 (July 1993).		
	LD	J. Best <i>et al.</i> , "Diabetic Dyslipidaemia", <i>59 Drugs</i> 5 1101-1111 (May 2000)		
	LE	P. Chong, <i>et al.</i> , "Current, New and Future Treatment in Dyslipidaemia and Atherosclerosis", <i>60 Drugs</i> 1 55-93 (July 2000)		
	LF	M. Brown <i>et al.</i> , "A Receptor – Mediated Pathway for Cholesterol Homeostasis", <i>232 Science</i> 34-47 (April 4, 1986)		
	LG	L. Lipka <i>et al.</i> , "Reduction of LDL-Cholesterol and Elevation of HDL-Cholesterol in Subjects with Primary Hypercholesterolemia by SCH 58235: Pooled Analysis of Two Phase II Studies", <i>JACC</i> 257A (Feb. 2000)		
	LH	Medical Economics, Co., Inc., <i>Physician's Desk Reference</i> , 207-208, 2054 (55 th Ed. 2001)		
	LI	K. Fassbender <i>et al.</i> , "Simvastatin Strongly Reduces Levels of Alzheimer's Disease β -Amyloid Peptides A β 42 and A β 40 in vitro and in vivo", <i>PNAs Early Edition</i> , www.phas.org/cgi/doi/10.1073/phas.081620098 (2001)		
	LJ	Andrx Announces Results of Alzheimer's Disease Clinical Study", <i>Andrx Corporate Release</i> (April 11, 2001)		
	LK	Andrx (ADRX): Pos Phase II Results Using Avicor in Alzheimer's: Str Buy; \$130", <i>US Bancorp Piper</i> , April 12, 2001		
	LL	Statins May Protect Against Alzheimer's Disease; much research needed", <i>Geriatrics</i> February 2001		
	LM	Dementia and Statins", <i>The Lancet</i> March 17, 2001		
	LN	Research & Development: Andrx Says Cholesterol Drug May Treat Alzheimers", <i>Reuters</i> April 11, 2001		
	LO	Cholesterol Drugs Ease Alzheimer's Damage; www.usatoday.com April 10, 2001		
	LP	Lovastation XL of Use in Alzheimer's? News Edge (May 2, 2001)		
	LQ	L. Refolo <i>et al.</i> , "Hypercholesterolemia Accelerates the Alzheimer's Amyloid Pathology in a Transgenic Morse Model, <i>Neurobiology of Disease</i> 321-331 (2000)		
	LR	D. Kang <i>et al.</i> , "Modulation of Amyloid β -protein Clearance and Alzheimer's Disease Susceptibility by the LDL Receptor – Related Protein Pathway", <i>Journal of Clinical Investigation</i> 106:9, 1159-1166 (Nov. 2000)		
	LS	Y.A. Kesaniemi, "Intestinal Cholesterol Absorption Efficiency in Man is Related to Apoprotein E Phenotype", <i>J. Clin. Invest.</i> 80(2) 578-81 (Aug. 1987)		
	LT	J. Busciglio <i>et al.</i> , "Generation of β -amyloid in the secretory pathway in neuronal and nonneuronal cells", <i>90 Proc. Nat'l. Acad. Sci, USA</i> , 2092-2096 <i>Neurobiology</i> (March 1993)		
	LU	L. Farrer <i>et al.</i> , "Assessment of Genetic Risk for Alzheimer's Disease Among first Degree Relatives", <i>Annals of Neurology</i> 25:5, 485-493 (May 1989)		
	LV	A. Goate <i>et al.</i> , "Segregation of a Missense Mutation in the Amyloid Precursor Protein Gene with Familial Alzheimer's Disease", <i>349 Nature</i> No. 6311, 704-706 (Feb. 21, 1991)		

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01	APPLICATION NO.: 10/700,909
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	LW	D. Mann <i>et al.</i> , "The Pattern of Acquisition of Plaques and Tangle in the Brains of Patients Under 50 years of Age with Down's Syndrome", 89 <i>J. Neuro. Sci.</i> , 169-179 (Feb. 1989)			
	LX	G. McKhann <i>et al.</i> , "Clinical Diagnosis of Alzheimer's Disease", 34 <i>Neurology No. 7</i> , 939-944 (July 1984)			
	LY	D. Selokoe, "Alzheimer's Disease: Genotypes, Pheontype and Treatments", 275 <i>Science</i> , 630-631 (Jan. 31, 1997)			
	LZ	C. Van Duijn, <i>et al.</i> , "Familial Aggregation of Alzheimer's Disease and Related Disorders: A collaborative Re-Analysis of Case-Control Studies", 20 <i>Int'l J. Epidemiology No. 2 (Suppl. 2)</i> , 513-520 (1991)			
	MA	T Nagahara <i>et al.</i> , "Dibasic (Amidcinoaryl) Propanoic Acid Derivatives as Novel Blood Coagulation Factor Xa Inhibitors", <i>J. Med. Chem</i> 37:1200-1207 (1994)			
	MB	Mellott <i>et al.</i> , "Acceleration of Recombinant Tissue-Type Plasminogen Activator Induced Reperfusion and Prevention of Reocclusion by Recombinant Antistatin, a selective factor Xa Inhibitor, in a Canine Model of Femoral Arterial Thrombosis", <i>Circulation Research</i> , 70:1152-1160 (1992)			
	MC	Sitko <i>et al.</i> , "Conjunctive Enhancement of Enzymatic Thrombolysis and Prevention of Thrombotic Reocclusion With the Selective Factor Xa Inhibitor, Tick Anticoagulant Peptide", <i>Circulation</i> , 85:808-815 (1992)			
	MD	Seymour <i>et al.</i> , 1994, <i>Biochemistry</i> , 33:3949-3959			
	ME	Markwardt, 1994, <i>Thrombosis and Hemostasis</i> , 72:477-479			
	MF	Mendall <i>et al.</i> , "C-Reactive Protein and its relation to cardiovascular risk factor: A population based cross sectional study", <i>BMJ</i> ; 312:1061-1065 (April 27, 1996)			
	MG	Ridker P. <i>et al.</i> , "Prospective Studies of C-Reactive Protein as a risk factor for cardiovascular disease", 46 <i>J. Investig. Med.</i> ; 8:391-395 (1998)			
	MH	Waters, D. <i>et al.</i> , "A Controlled Clinical Trial to Assess the Effect of a Calcium Channel Blocker on the Progression of Coronary Atherosclerosis", <i>Circulation</i> ; 82:1940-1953 (1990)			
	MI	Fleckenstein, 1985, <i>Cir. Res. Vol 52 (Suppl. 1)</i> 13-16			
	MJ	Fleckenstein, 1983, "Experimental Facts and Therapeutic Prospects", <i>John Wiley, New York</i> , pp. 286-313			
	MK	McCall, D., 1985, " <i>Curr. Pract. Cardiol.</i> Vol. 10, 1-11			
	ML	Remington 1995, "The Science and Practice of Pharmacy, (19 th Ed. 1995) p. 963			
	MM	M. Chistie <i>et al.</i> , "Early - Onset Amyloid Deposition and Cognitive Deficits in Transgenic Mice Expressing a Double Mutant Form of Amyloid Precursor Protein 695", 276 <i>J. Biol. Chem. No. 24</i> ; 21562-70 (June 15, 2001)			
	MN	C. Janus <i>et al.</i> , "A β Peptide Immunization Reduces Behavioral impairment and Plaques in a Model of Alzheimer's Disease", 408 <i>Nature</i> 21/28; 979-982 (Dec. 2000)			
	MO	Manual of Laboratory Operations, "Lipid Research Clinics Program Report, Washington, D.C., U.S. Dept. of Health, Education and Welfare Publication; 1:75-628 (1974)			
	MP	Steiner, PM <i>et al.</i> , "Standardization of Micromethods for Plasma Cholesterol, Triglyceride and HDL-Cholesterol with the Lipid Clinic's Methodology [abstract], <i>J. Clin. Chem. Clin. Bichem</i> ; 19:850 (1981)			

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: CV06093US01	APPLICATION NO.: 10/700,909
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	MQ	Steele WG, <i>et al.</i> , "Enzymatic Determinations of Cholesterol in High Density Lipoprotein Fractions Prepared by Precipitation Technique," <i>22 Clin. Chem.</i> ; 1:98-101 (1976)			
	MR	Salen <i>et al.</i> , "Increased Sitosterol Absorption, Decreased Removal and Expanded Body Pools Compensate for Reduced Cholesterol Syntheses in Sitosterolemia with Xanthomatosis", <i>J. Lipid Res.</i> ; 30 :1319-1330 (1989)			
	MS	Lutjohann <i>et al.</i> , "Sterol Absorption and Sterol Balance in Phytosterolemia Evaluated by Deuterium-Labeled Sterols: Effect of Sitostanol Treatment", <i>J. Lipid Res.</i> ; 36 :8; 1763-1773 (1995)			
	MT	Zhang <i>et al.</i> , "Calpain Inhibitor I Increases B- Amyloid Peptide by Inhibiting the Degradation of the Substrate of γ - Secretase" 274 J. Biol. Chem. , 13:8966-8972 (1999)			
	MU	Zhang <i>et al.</i> , "Biochemical Characterization of the γ -Secretase Activity that Produces B-Amyloid Peptides", <i>Biochemistry</i> 40 :5049-5055 (2001)			
	MV	Ida <i>et al.</i> , "Analysis of Heterogeneous BA4 Peptides in Human Cerebrospinal Fluid and Blood by a Newly Developed Sensitive Western Blot Assay", 271 J. Biol. Chem. ; 37:22908-22914 (1996)			
	MW	Lichtlen, P.R. <i>et al.</i> , 1990, <i>Lancet</i> ; 335 :1109-1113			
	MX	Bays <i>et al.</i> , "Effectiveness and Tolerability of Ezetimibe in Patients with Primary Hypercholesterolemia: Pooled Analysis of Two Phase II Studies", <i>Clinical Therapeutics</i> , 23 :1209-1230 (2001)			
	MY	E. Leitersdorf <i>et al.</i> , "Cholesterol absorption inhibition: filling an unmet need in lipid-lowering management", <i>European Heart Journal Supplement</i> , 3 :E17-E23 (June 2001)			
	MZ	Bauer <i>et al.</i> , "Ezetimibe Does not Affect the Pharmacokinetics or Pharmacodynamics of Warfarin", <i>Clinical Pharmacology and Therapeutics</i> , 69 :2 p5 (Mar. 6-10, 2001)			
	NA	Keung <i>et al.</i> , "Ezetimibe Does Not Affect the Pharmacokinetics of oral Contraceptives", <i>Clinical Pharmacology and Therapeutics</i> , 69 :2 p55 (Mar. 6-10, 2001)			
	NB	Kosoglou <i>et al.</i> , "Pharmacodynamic interaction between fenofibrate and the Cholesterol Absorption Inhibitor Ezetimibe", <i>Workshops Lipid Lowering Drugs 72nd EAS Congress</i> , p. 38 (May 21-23, 2001)			
	NC	T. Kosoglou <i>et al.</i> , "Coadministration of Ezetimibe and Fenofibrate Leads to Favorable Effects On Apo CII and LDL Subfractions", <i>Posters 11. Lipid Lowering Drugs/Novel, 72nd EAS Congress</i> , p. 89 (May 21-23, 2001)			
	ND	L. Reyderman <i>et al.</i> , "Assessment of a Multiple-Dose Drug Interaction Between Ezetimibe and Gemfibrozil", Presented at XIV Int'l Symp. on Drugs Affecting Lipid Metabolism (DALM) N.Y. (Sept. 9-12, 2001)			
	NE	P. Statkevich <i>et al.</i> , "Ezetimibe Does Not Affect the Pharmacokinetics and Pharmacodynamics of Glipizide", <i>Clinical Pharmacology & Therapeutics</i> , 69 :67 (March 6-10, 2001)			
	NF	Knopp <i>et al.</i> , "Effect of Ezetimibe on Serum Concentrations of Lipid-Soluble Vitamins", <i>Posters 11. Lipid Lowering Drug/Novel 72nd EAS Congress</i> , p. 90 (May 21-23, 2001)			

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	NG	Kosoglou <i>et al.</i> , "Pharmacodynamic Interaction Between Fenofibrate and the Cholesterol Absorption Inhibitor Ezetimibe", <i>Workshops Lipid Lowering Drugs, 72nd EAS Congress</i> , p. 38 (March 6-10, 2001)		
	NH	Bays <i>et al.</i> , "Low-Density Lipoprotein Cholesterol Reduction By SCH 58235 (Ezetimibe), A Novel Inhibitor of Intestinal Cholesterol Absorption, in 243 Hypercholesterolemic Subjects: Results of a Dose-Response Study", <i>XII International Symposium on Atherosclerosis, Stockholm, Sweden (June 25-29, 2000)</i>		
	NI	Castaner <i>et al.</i> , "Ezetimibe – Hypolipidemic Cholesterol Absorption Inhibitor", <i>Drugs of the Future</i> , 25(7) :679-685 (2000)		
	NJ	Lipka <i>et al.</i> , "Reduction of LDL-Cholesterol and Elevation of HDL-Cholesterol in Subjects with Primary Hypercholesterolemia by Ezetimibe (SCH 58235): Pooled Analysis of Two Phase II Studies", <i>American College of Cardiology Annual Meeting, Anaheim, CA (March 12-15, 2000)</i>		
	NK	Van Heek <i>et al.</i> , "Comparison of the activity and disposition of the novel cholesterol absorption inhibitor, SCH58235, and its glucuronide, SCH60663", <i>British Journal of Pharmacology</i> , 129 :1748-1754 (2000)		
	NL	Van Heek <i>et al.</i> , 2000, "The potent cholesterol absorption inhibitor, ezetimibe, is glucuronidated in the intestine, localizes to the intestine, and circulates enterohepatically", <i>XII International Symposium of Atherosclerosis, Stockholm Sweden (June 25-29, 2000)</i>		
	NM	Iannucci <i>et al.</i> , "Metabolism of SCH 58235 in the Human, Rat and Dog", <i>47th ASMS Conference on Mass Spectrometry and Allied Topics, Dallas, TX (June 13-17, 1999)</i>		
	NN	Reiss <i>et al.</i> , "An Enzymatic Synthesis of Glucuronides of Azetidinone-based Cholesterol Absorption Inhibitors", <i>Bioorganic & Medicinal Chemistry</i> , 7 :2199-2202 (1999)		
	NO	Rosenblum <i>et al.</i> , "Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption", <i>J. Med. Chem.</i> 41 :973-980 (1998)		
	NP	Vaccaro <i>et al.</i> , "Sugar-Substituted 2-Azetidinone Cholesterol Absorption Inhibitors: Enhanced Potency by Modification of the Sugar", <i>Bioorganic & Medicinal Chemistry Letters</i> , 8 :313-318 (1998)		
	NQ	Zaks <i>et al.</i> , "Enzymatic Glucuronidation of a Novel Cholesterol Absorption Inhibitor, SCH 58235", <i>Applied Biochemistry and Biotechnology</i> , 73 :205-214 (1998)		
	NR	W. Insull <i>et al.</i> , "Postmenopausal Hypercholesterolemic Women Derive Additive Benefit from Raloxifene and Simvastatin on Lipid Parameters", <i>World Heart Federation 6th International Symposium on Global Risk of Coronary Heart Disease and Stroke – Abstract Book</i> , p. 35 (June 12-15, 2002)		
	NS	L. Simons <i>et al.</i> , 2002, "Ezetimibe added to on-going statin therapy for treatment of primary hypercholesterolemia: Efficacy and safety in patients with Type 2 diabetes mellitus", presented at the 38 th Annual Meeting of the EASD, September 1-5, 2002		
	NT	C. Allain <i>et al.</i> , 1974, "Enzymatic Determination of Total Serum Cholesterol", <i>Clinical Chemical</i> , 20 :470-475		
	NU	R. Mayrhofer <i>et al.</i> , 1980, "Simple-Preparation of 3-Benzylidene-2-azetidinones", <i>Synthesis</i> , 247-248		

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	NV	Burrier, R.E. <i>et al.</i> , 1994, "Demonstration of a Direct Effect on Hepatic Acyl CoA:Cholesterol Acyl Transferase (ACAT) Activity By An Orally Administered Enzyme Inhibitor in the Hamster", <i>Biochemical Pharmacology</i> 47:15451551		
	NW	Burrier, R.E. <i>et al.</i> , 1994, "The Effect of Acyl CoACholesterol Acyltransferase Inhibitor on the Uptake, Esterification and Secretion of Cholesterol by the Hamster Small Intestine", <i>The Journal of Pharmacology and Experimental Therapeutics</i> 272:156-163		
	NX	E.F. Binder <i>et al.</i> , "Effects of Hormone Replacement Therapy on Serum Lipids in Elderly Women. A Randomized, Placebo-Controlled Trial", <i>134 Ann. Intern. Med.</i> 9:754-760 (May 1, 2001)		
	NY	MR Haymart <i>et al.</i> , "Optimal Management of Dyslipidemia in Women and Men", <i>2 J. Gend. Specif. Med.</i> 6:37-42 (Nov. - Dec. 1997)		
	NZ	"Framingham Heart Study Analysis Reveals Some Primary Prevention Subgroups Are Being Overlooked", <i>Heartwire</i> (April 12, 2001)		
	OA	"Detection Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), "Third Report of the National Cholesterol Education Program (NCEP)", <i>NIH Publication No. 01-3670</i> (May 2001)		
	OB	Van Heek <i>et al.</i> , "Ezetimibe, A Potent Cholesterol Absorption Inhibitor, Normalizes Combined Dyslipidemia in Obese Hyperinsulinemic Hamsters", <i>50 Diabetes</i> 1330-1335 (June 2001)		
	OC	"Additional Statins Show Anti-Inflammatory Effect", <i>103 Circulation</i> 1933-35 (April 17, 2001)		
	OD	H. Hauser, <i>et al.</i> , "Identification of a Receptor Mediating Absorption of Dietary Cholesterol in the Intestine", <i>Biochemistry</i> 37:17843-17850, 1998		
	OE	G. Salen, <i>et al.</i> , "Sitosterolemia", <i>Journal of Lipid Research</i> 33:945-955, 1992		
	OF	Stedman's Medical Dictionary, 27 th Edition, pg. 1381		
	OG	Stuart B. Rosenblum <i>et al.</i> , Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption, <i>J. Med. Chem.</i> 41:973-980 (1998)		
	OH	Remington's Pharmaceutical Sciences, 18 th ed. 1990 p. 1319, 1633-1647		
	OI	Baker S G <i>et al.</i> , Treatment of homozygous familial hypercholesterolaemia with probucol, <i>South African Medical Journal</i> (1982)		
	OJ	R. Milanese <i>et al.</i> , Xantomii E Ipercolesterolemia: Prevalenza, Diagnosi e Terapia, <i>Chron. Derm.</i> 455-61 (1990)		
	OK	"Study showed ezetimibe significantly reduced levels of LDL cholesterol or "bad" cholesterol in patients" <i>Schering Press Release</i> 1-3 (2001)		
	OL	Kosoglou <i>et al.</i> , "Pharmacodynamic interaction between fenofibrate and the cholesterol absorption inhibitor ezetimibe" <i>Atherosclerosis</i> (2):3(2001)		
	OM	Davis <i>et al.</i> , "The Synergistic Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor, Ezetimibe, in Combination with 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase Inhibitors in Dogs" <i>Metabolism</i> 50(10):1234-1241(2001)		
	ON	Thompson, G.R. <i>et al.</i> , "Novel lipid-regulating drugs" <i>Expert Opinion on Investigational Drugs</i> 9(11):2619-2628 (2000), XP008011782		
	OO	Kosoglou, T. <i>et al.</i> , "Coadministration of ezetimibe and fenofibrate leads to favorable effects on Apo CII and LDL subfractions" <i>Atherosclerosis</i> 2:89 (2001), XP001132089 abstract		
	OP	Gilber R. Thompson <i>et al.</i> , Novel lipid-regulating drugs, Ashley Publications Ltd. ISSN 1354-3784, 2000, pp. 2619-2628		
	OQ	Belamarich P.F. <i>et al.</i> , Response to diet and cholestyramine in a patient with sitosterolemia, <i>Pediatrics</i> , ISSN 0031-4005, Dec. 1990		
	OR	Salen G. <i>et al.</i> , Lethal atherosclerosis associated with abnormal plasma and tissue sterol composition in sitosterolemia with xanthomatosis, <i>Journal of lipid research</i> , ISSN 0022-2275, Sept. 1985		

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OS	Sorbera <i>et al.</i> , Netoglitazone, <i>Drugs of the Future</i> , 2002, 27(2): 132-139			
OT	Michel Farnier, Nouvelles approches médicamenteuses dans le traitement des dyslipidémies, <i>MT Endocrinologie</i> , 2002, 4:252-259			
OU	Berger <i>et al.</i> , Physiological and Therapeutic Roles of Peroxisome Proliferator-Activated Receptors, <i>Diabetes Technology & Therapeutics</i> , 2002, 4:163-174			
OV	U.S. Serial No. 10/791,910			
OW	U.S. Serial No. 10/792,346			
OX	U.S. Serial No. 10/791,979			
OY	U.S. Serial No. 10/701,244			
OZ	U.S. Serial No. 10/639,900			
PA	Cholesterol Drugs May Reverse MS Symptoms, Studies in Mice show statins may treat Multiple Sclerosis – <i>CNN.com/Health</i> , Wednesday, November 6, 2002 posted: 4:30 PM EST (2130 GMT)			
PB	D. Grady, Health, Antiolesterol Drug Found to Help Paralytic Mice, <i>www.nytimes.com/2002/11/07/health/07DRUG.html</i>			
PC	S. Youssef <i>et al.</i> , Atorvastatin, a HMG-CoA Reductase Inhibitor, Promotes a Th2 Bias and Reversal of Paralysis in Chronic Relapsing Autoimmune Encephalomyelitis, <i>Neurology</i> 58 April 2002 (Suppl 3), A384-A385			
PD	M. Soilu-Hanninen <i>et al.</i> , Semliki Forest Virus Infects Mouse Brain Endothelial Cells and Causes Blood-Brain Barrier Damage, <i>Journal of Virology</i> , Oct. 1994, 6291-6298			
PE	Chapter 15 Animal Models for Autoimmune and Inflammatory Disease, Unit 15.1 Experimental Autoimmune Encephalomyelitis in the Mouse, <i>Current Protocols in Immunology</i> , November 6, 2002			
PF	J. Pope <i>et al.</i> , Flow Cytometric and Functional Analyses of Central Nervous System-Infiltrating Cells in SJL/J Mice with Theiler's Virus-Induced Demyelinating Disease – Evidence for a CD4+ T Cell-Mediated Pathology, <i>The Journal of Immunology</i> 4050-4058			
PG	H. Butzkueven <i>et al.</i> , LIF receptor signaling limits immune-mediated demyelination by enhancing oligodendrocyte survival, 2002 <i>Nature Publishing Group- Nature Medicine</i> , 8:6 613-619 (June 2002)			
PH	I. Grewal <i>et al.</i> , CD62L Is Required on Effector Cells for Local Interactions in the CNS to cause Myelin Damage in Experimental Allergic Encephalomyelitis, <i>Immunity</i> , 14:291-302 (March 2001)			
PI	E. Tran <i>et al.</i> , Induction of experimental autoimmune encephalomyelitis in C57BL/6 mice deficient in either the chemokine macrophage inflammatory protein -1 α or its CCR5 Receptor, <i>Eur. J. Immunol.</i> , 30:1410-1415 (2000)			
PJ	F. Giubilei <i>et al.</i> , Blood cholesterol and MRI activity in first clinical episode suggestive of simple sclerosis, <i>Aeta Neurol Scan</i> , 106:109-112 (2002)			
PK	R.O. Weller, Neurology & Applied Neurobiology, <i>Blackwell Scientific Publications</i> , 20:2 April 1994			
PL	R. Berkow <i>et al.</i> , The Merck Manual of Medical Information – Home Edition, <i>Pocket Books</i> , Title of Chapter 68 347-350 (1997)			
PM	Pelfrey, C., Actrims – Ectrims 2002 (Part II), Baltimore, MD USA, 18-21- September 2002, <i>The Investigational Drugs Database ALERTS</i>			
PN	P. Reaney, Cholesterol Drugs may help MS Patients, <i>Yahoo Financial News</i> , Wednesday, November 6, 2002 pm ET			
PO	H. Wekerle, Tackling Multiple Sclerosis, <i>Nature</i> , 420:39-84 (2002)			
PP	S. Youssef <i>et al.</i> , The HMG-CoA reductase inhibitor, atorvastatin, promotes a Th2 bias and reverses paralysis in central nervous system autoimmune disease, <i>Nature</i> , 420:78-84 November 7, 2002			

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	PQ	Shestopalov, A.M. <i>et al.</i> , Cyclization of Nitriles .XI. Synthesis and reactions of 3-Amino-2-Carboxythieno[2,3-b]-Pyridines, <i>Zhurnal Organicheskoi Khimii</i> , 20:9 1818-1827			
	PR	Shestopalov, A. M. <i>et al.</i> , Cyclization of Nitriles .XIX. Synthesis and reactions of the derivatives of 2-oxo-and 2-thioxo-2,5,6,7-Tetrahydro-1H-Pyrindines, <i>Zhurnal Organicheskoi Khimii</i> 22:6 1163-1168			
EXAMINER			DATE CONSIDERED		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					

Applicant: John R. Erbey II, et al.
 Serial No.: 10/700,909 Atty.: AMC:sa
 Filed: 11/04/2003 Case No.: CV06093US01
 For: Methods and Therapeutic Combinations...

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- ☒ Certificate of Mailing PTO/SB/92 (1 page)
- ☐ Response Transmittal Form (PTO/SB/21)
- ☐ Fee Transmittal (PTO/SB/17) In Duplicate
- ☐ Response To Notice to File Missing Parts (____pages)
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- ☐ Declaration/Power of Attorney (Exec./Unexec./Copy) (____pages)
- ☐ Sequence Listing (____pages)
- ☐ Sequence Listing Statement (____pages)
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